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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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BAYER CORPORATION
PATENT DEPARTMENT
100 BAYER ROAD
PITTSBURGH, PA 15205

EXAMINER

SHEIKH, HUMERA N

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 02/21/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/768,657

Applicant(s)

CABRERA, FRANCISCO

Examiner

Humera N Sheikh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 6) ☐ Other:

DETAILED ACTION

Status of the Application

The US Patent No. 5,152,986 was incorrectly listed as 5,512,986 in the Information Disclosure Statement. The Examiner has corrected this error.

Status of the Claims

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear as to what Applicant intends to convey by "quinolone- or naphthyridonecarboxylic acid" in claim 1, which renders the claim indefinite. The term "quinolone- or naphthyridonecarboxylic acid " is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The expression is indefinite because it can be interpreted in two various ways: it can be, either (1) quinolone- or naphthyridonecarboxylic acid or (2) quinolonecarboxylic acid or naphthyridonecarboxylic acid. It is unclear which interpretation is intended.

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The term "insoluble matrix" is indefinite because it is unclear, as to which solvents the quinolone- or naphthyridonecarboxylic acid is insoluble in.

The term "polyethylene glycol polyvinyl pyrrolidone" is indefinite because it contains a typographical error. The terms are missing a comma and therefore are being interpreted as one word, rather than two. Appropriate correction is requested.

Regarding claim 8, Examiner suggests the use of the additional word "agent" after the term "active" in line 26.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2 and 6-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Lange et al. (US Pat. No. 5,152,986) or Vetter et al. (US Pat. No. 5,808,076).

Lange et al. disclose a solid orally administered medicament preparation comprising quinolonecarboxylic acid derivatives, polyethylene glycols and polyvinyl alcohols used in feedstuffs for animals for the improvement of masking flavor and intake of the composition (see reference column 1, lines 1-11); (column 2, lines 48-66); (column 3, lines 36-47); (column 5, lines 10-32); (column 6, lines 19-26, 52-66); (column 11, lines 21-52); (column 12, lines 1-31).

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Claims 1-2 and 6-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Vetter et al.

Vetter et al. disclose a solid oral preparation comprising quinolone- or naphthyridonecarboxylic acids, polyethylene glycols and polyvinyl alcohols for use in feed formulations, which mask bitter flavoring and fight bacterial infections in humans and animals (see reference column 1, lines 1-45); (column 2, lines 44-58); (column 3, lines 50-67); (column 4, lines 1-27); (column 5, lines 19-35); (column 8, lines 10-45).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lange et al. (US Pat. No. 5,152,986) or Vetter et al. (US Pat. No. 5,808,876) in view of Pollinger et al. (US Pat. No. 5,695,784).

As pointed out above, Lange et al. teaches the use of a solid oral preparation comprising quinolonecarboxylic acid, polyethylene glycols and polyvinyl alcohol wherein the preparation is admixed into animal feed to mask the bitter taste and therefore, improve the animal's intake and consumption of the feed formulation (see reference column 1, lines 1-11); (column 2, lines 48-66); (column 3, lines 36-47); (column 5, lines

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10-32); (column 6, lines 19-26, 52-66); (column 11, lines 21-52); (column 12, lines 1-31).

As pointed out above, Vetter et al. teach a solid, homogeneously dispersed oral preparation comprising quinolone- or naphthyridonecarboxylic acids, polyethylene glycols and polyvinyl alcohols for use with taste-sensitive animals for the treatment of bacterial infections (see reference column 1, lines 1-45); (column 2, lines 44-58); (column 3, lines 50-67); (column 4, lines 1-27); (column 5, lines 19-35); (column 8, lines 10-45).

Lange et al. or Vetter et al. are lacking in the teachings of the use of shellac in the quinolonecarboxylic acid formulation. It is well within the skill of the pharmaceutical art that various binders and film-forming agents can be implemented, in combination, to increase the mechanical stability and strength of oral preparations. Such skill is also evident from the reference of Pollinger et al. (US Pat. No. 5,695,784). Pollinger et al. teach the use of flavor-masked pharmaceutical compositions comprising naphthyridone- and quinolone-carboxylic acid, polyethylene glycol, polyvinyl alcohol and shellac (see reference column 1, lines 30-67); (column 4, lines 9-59); (column 5, lines 7-15, 45-53). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use quinolone- or naphthyridonecarboxylic acids to mask ill-flavored compositions in feed or foodstuff applications, with the expected result of obtaining an edible, improved tasting, therapeutic composition for the treatment of bacterial infections in humans and animals.

Lange et al. or Vetter et al. do not teach the exact claimed ratios. However, in the absence of showing the criticality, it is deemed obvious to manipulate the ranges to obtain the best possible results.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera Sheikh whose telephone number is (703) 308-4429. The examiner can normally be reached on Monday through Friday from 7:00A.M. to 4:30P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

THURMAN R. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600